

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Conference Leader: Cassandra Black
January 10, 2008
2:00 pm ET

Operator: Good afternoon. My name is (Rebecca) and I will be your conference facilitator today.

At this time I would like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open Door Forum on Medicare Part B Competitive Acquisitions Program Vendor Bidding.

All lines have been placed on mute to prevent any background noise.

After the speakers remarks there will be a question and answer session. If you would like to ask a question during this time simply press star then the number 1 on your telephone keypad. If you would like to withdraw your question press the pound key.

Thank you Ms. Highsmith. You may begin your conference.

Natalie Highsmith: Thank you (Rebecca). And Happy New Year to everyone and thank you for joining us for this special Open Door Forum on Medicare Part B Competitive Acquisition Program otherwise known as CAP Vendor Bidding.

This special open door is limited to entities that are interested in bidding to be an approved CAP vendor. Representatives from the CAP designated carrier and from CMS will be available to answer questions about the CAP and the vendor bidding process.

CMS anticipates releasing a solicitation for contracts to be awarded to vendors to supply drugs for the CAP. The vendor bidding period will begin on January 14, 2008 and end on February 15, 2008. These vendor contracts will be effective January 1, 2009 through December 31, 2011.

The purpose of this call again is to respond to potential CAP vendors only. Questions pertaining to the CAP physicians will be dealt with in an upcoming CAP physician at the contractor teleconference being held later on this month.

And when we come to the Q&A portion, as you remember the operator gave you numbers to, assigned to you, and when it comes to the Q&A you will be identified on the line as your number. If you wish announce your name during the Q&A please feel free to do so, otherwise you can just go anonymously as your number to ask your question. And there is an e-mail address to send questions and comments and that e-mail address is mma303ddrugbid@cms.hhs.gov, that's mma303ddrugbid@cms.hhs.gov.

Now I will turn the call over to Mr. Don Thompson who is the Acting Deputy Director of the Hospital and Ambulatory Policy Group here at CMS. Don.

Don Thompson: Thank you. I'd like to thank everyone for being on the call today. We're looking forward to having a good discussion interchange, be able to share information with you and answer your questions with respect to the bidding process.

As you know, the competitive acquisition program is an alternative to the average sales price system under which physicians buy and bill drugs. Under this program physicians are able to elect to receive the drugs from vendors and then the vendors bill the program. The program's been very successful and we're looking forward to very robust program expansion in this next round of bidding and hopefully the level of interest we're seeing on this call and in the months prior to this people have been inquiring about the program and it's bidding.

We are very hopeful that we will see again a robust program expansion in this next bidding cycle. We've made some improvements as the program has matured since this is the second cycle around. For example the law was changed to allow us to pay the vendors more timely than was true when we initially bid this, initially set up the program, there's some mechanisms to add new drugs to the program.

An example of that has been (Lucentis), so even after the program begins throughout the length of the contract should new drugs come on the market it would be of interest to the physicians and beneficial for the beneficiaries in the program. We have the ability to add those in and we think with these enhancements and the experience we've learned and what we've been able to accomplish over the last few years, we think we've gotten the program to the point where it's ready for again a much, we're hoping, a much broader audience, more vendor participation, more physician participation and this is just one step in that process.

So with that, I will turn it over to (Cassie) Black who is going to talk a little bit about the call today and then we'll take some questions.

(Cassie) Black: Great. Thanks very much Don. Glad to be with all of you today. Before I get started I'd like to mention a couple other members of the CAP team who will be answering questions and speaking to you. One is (Edmund Kasaitis) and the other is (Bonny Dahm).

As Don mentioned, CAP was an MMA provision and it's an alternative to the ASP payment methodology for Part B drugs. If a physician chooses to participate in the CAP program, they would agree to get all the drugs on the CAP drug list from the vendor that they have selected. The physician places a patient-specific order with their vendor and then the approved CAP vendor supplies the drug to the physician's office, the vendor bills Medicare for the drugs and the beneficiary and his or her supplemental insurer for any applicable co-insurance.

As Don mentioned there were a few changes in the program that were put into place last April and now instead of waiting to pay claims after there's a match between the physician's claim for administering the drug and the vendor's claim for the drug, we pay the claim for the drug up front and do the verification of drug administration and a medical necessity review on a post-paid basis using a statistical sampling process.

In addition, as I think Don mentioned, we also are continuing to look for ways to improve the program and in last years Physician Fee Schedule Rule, which just took effect January 1, we made a couple changes that we think will be attractive to CAP physicians. One of those was that originally we required that CAP drug administration claims needed to be submitted within 15 days. We've now extended that window to 30 days.

And then in addition, we've given the physicians a little more time to come in and try the program and if they discover that the model is not a good fit, that

they can withdraw from the program within the first 60 days and even after that if they discover that the model just isn't working for them, they can petition CMS and ask for withdrawal. And we think that this will work with some physicians who have never tried something like this before, may be willing to come in and see if the model fits them.

As Don mentioned in his remarks, this is our second round of CAP bidding. We went through bidding the first time in 2005 and 2006. We can have up to five vendors in the CAP program. Initially we started with one vendor, BioScrip, and the CAP began paying claims on July 1, 2006. So the current phase of the program goes until December 31, 2008. There currently is one drug category with about 180 plus drugs.

We also can make further geographic areas for the program but we started out with one geographic region, so that includes all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam and the Northern Marianas.

So as a result of the bidding that we're getting ready to go through, a three-year contract will be awarded to vendors who can do certain things, and briefly those are need to have and maintain sufficient means to acquire and deliver competitively biddable drugs within the specified contract area, which again is the territory I just mentioned, arrangements in effect for shipping at least five days a week and the competitively biddable drugs under the contract and the means to ship those drugs in emergency situations, and to have in place quality service, financial performance and solvency standards and a grievance and appeals process for dispute resolution.

Approved CAP vendors must also qualify for enrollment in Medicare and it will be enrolled as a new provider specialty. Bidders must agree to apply at

least one NDC and on the CAP drug list. (Edmund Kasaitis) will be going into more detail on the drug provisions of the CAP program.

For 2007 approximately 3,300 physicians have participated in the CAP nationwide. For 2008 approximately 2,300 physicians are enrolled in the program at this point. We are about to undergo a second physician election period for 2008. We wanted to give physicians a chance to participate in the program because of some of the changes that we made in the Physician Fee Schedule Rule. By the time those rules were announced the bidding period had almost closed.

So I wanted to give you an overview of what we're looking at for those bidding timelines. As Natalie mentioned, the bidding period opens on January 14th. Revised bid forms, the drug bid sheet will be posted on the CAP Web site. Right now if you go onto our Web site you can look at the bidding forms and the documents we used for the last bidding period. These documents will be only slightly revised for the next bidding period. There is also the list of CAP drugs and the weights, those will be updated and reposted as well.

We also plan to post other information about CAP participation, the top drugs in the program, other information that might be useful to you later on next week. The bidding period closes on Friday, February 15, 2008. All bids must be received at CMS by 5:00 pm Eastern Standard Time on that day.

Our tentative plans for the rest of the period are that we plan to complete our bid evaluation and 855 review by the end of April 2008. In May 2008 we plan to identify the bidders in a competitive range and offer contracts. We plan on having signed contracts early in the summer and then carry on with training for the new vendors. Between October 1, 2008 and November 15th there be

physician election will take place and then on January 1, 2009 the new contract period begins.

At the time of application bidders will submit two electronic copies of the completed vendor application and bid form and the completed drug bid form, which is an Excel spreadsheet on compact disks, and one signed paper copy of these documents. In addition, bidders will also submit one paper 855B form with original signatures and one copy. As I mentioned a few minutes ago, all these documents must be received in our offices at CMS all by 5:00 pm Eastern Standard Time on Friday, February 15th and those documents should be addressed to my attention, which is: Cassandra Black, CMS, attention Vendor Application, C4-01-26, 7500 Security Boulevard, Baltimore, Maryland 21244.

All of this information will be posted on our Web site, so don't worry that you might not be able to copy it all down quickly. We are having you send all the documents here and that what we overnight the 855B applications to Noridian, the CAP designated carrier. They will handle that part of the process, so they will be reviewing and following up and making the final determinations.

Now I'd like to give you an overview quickly of what's in the bidding documents. The vendor applications are comprised of two pieces with instructions included for each. The first is the vendor application and bid form and the second is the drug bid form. In addition as I mentioned a minute ago in order to be an approved CAP vendor you also have to be approved as a Medicare supplier and in order to do that you need to submit an 855B form. In order to be enrolled as a CAP vendor and a Medicare supplier, an applicant, including any subcontractor, subsidiaries or business affiliates must be licensed in such a manner that will allow them to supply CAP drugs in all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands,

American Samoa, Guam and the Northern Marianas if the applicant is selected as an approved CAP vendor.

For reference purposes, the 855B form may be viewed and downloaded from the form section of the CMS Web site. Additional information about the 855B application process may be found at the CAP designated carrier's Web site and there's a link on our competitive bidding Web site to the designated carrier's Web site.

Basically when you're reviewing the CAP application documents what you need to keep in mind is that all the requirements for the program are consistent with what we put in our Federal Register notices and the statutes, so if you want to look at all of the documents that are out there you can go on our Web site. There's a section called CAP proposed and final rules. That will give you some good guidance on how we interpret these regulations.

When you submit your application to us, please mark any privileged or confidential items. This is your responsibility. Be sure the form is complete. Answer all questions. Do not leave blanks. A zero and a blank are not the same.

The first two pages of the application are a certification agreement which contain the requirement for the CAP program. By signing this agreement the applicant is stating that they agree that all of the information submitted is correct. The next information you fill in is about your management and operations, your experience and capabilities, next comes a section on financial information, your business volumes, balance sheets, profit and loss statement. All information submitted must come from the organization whose sole legal name is identified on Page 4 of the vendor application. Page 6 has information on your licensure and sanctions; Page 7 has the compliance plan and

operational aspects. A fully developed compliance plan should be submitted at the time of application. It also contains information on customer service and prescription order processing and shipping requirements and how you plan to implement those. Pages 8 and 9 have attachments that you will provide which cover the history of the organization, subcontractors you plan to use. All financial statements submitted must be audited. Page 10 has an example of the table that shows how CAP drug bid prices should be submitted. An updated version of the spreadsheet will be posted on our Web site on Monday, January 15th.

Now I'm going to turn it over to (Edmund Kasaitis) to talk more about the drug bidding part of the program.

(Edmund Kasaitis): Thanks (Cassie). Good afternoon everybody. So in addition to responding to information that's requested on the sender application and bid form your actual bid prices will be submitted on the vendor bidding sheet. This is an Excel spreadsheet that contains two worksheets, one is an instruction sheet and the other is a table that contains the CAP drugs and their weights.

You'll be filling in your bid prices for each (HCPCS) code that is listed and the (NDCs) that you plan to supply under each (HCPCS) code. As mentioned earlier, the CAP still consists of one geographic area which is the United States and its territories as well as the District of Columbia and there is still one CAP category of drugs. The drug list is similar to the 2006 bid list which is posted on the CAP Web sites CAP Bidder Background page and it's very similar to the 2008 CAP drug list which is on the vendor page and the physicians page on the CAP Web site. The changes are that we have removed several low cost and several low volume items compared to previous lists.

There are about 180 drugs, meaning 180 (HCPCS) codes in the bidding list. All but three of these drugs are weighted drugs. You must bid on each of these drugs and it's also your responsibility to be sure that the composite bid price for the weighted drugs does not exceed the January 2008 ASP payment amount. You calculate a composite bid by multiplying your bid price by the weight. And on the vendor bidding sheet supplied by us, the sum of your composite bid prices must be less than or equal to the sum of the ASP composite payment for January 2008.

Bids on individual weighted drugs can exceed the drugs January ASP payment amount, but your composite bid for those weighted drugs, that's the sum of the composite bids, cannot exceed the composite of the CAP drugs ASP payment amounts.

The unweighted drugs, there are only three of them in this bidding cycle; they're at the very bottom of that second spreadsheet. In here your bid for each of the unweighted drugs must be less than or equal to the ASP payment amount for that specific drug for the first quarter of calendar year 2008. The ASP payment amount limits are on the January 2008 ASP price file. The simplest way to get there is if you go to the CAP overview page, go down to the very bottom to the related links and sites inside CMS, click on Medicare Part B drug average sales price. And there's a link to the 2008 files on the top left hand of that page.

Additional details about the composite bid process were also published in the July 6, 2005 interim final rule and that's in the Federal Register in Volume 70, Page 39072.

I also just wanted to give you a few reminders in addition to what (Cassie) said about being sure that you fill in all of the information that we ask for and

submit information for all the addenda on the vendor application and bid form and also not submitting any blanks, put in zero if you mean zero. We would also like to remind you that be sure that the spreadsheet is filled out completely. You must bid on each line item for the weighted and the unweighted drugs.

We also anticipate that for many of these drugs, you will plan to supply more than one product, or more than one NDC code under each (HCPCS) code. So remember to separate the NDC numbers that you plan for provide under each (HCPCS) code with a comma on the vendor bidding spreadsheet. Also please be sure that your spreadsheet can be read by Excel 2003. That's what we're going to be using here.

Please don't send the response as just a PDF document. We can't easily conduct our analysis on that. If you want to send a PDF document as an addendum you can do that. That is not a requirement however. And in addition to providing satisfactory responses to the vendor application and bid form in order to be eligible for a contract to supply CAP drugs the bidder must submit one of the five lowest bids for the single drug category. So we're only taking the five lowest bidders who meet all of our criteria.

And other than that I'm going to turn it back over to (Cassie).

(Cassie) Black: Thanks very much (Edmund). I just had a few more details and then we'll open it up to your questions. I wanted to give you some tips on completing the 855B form. Be sure when you send it in that you sign the appropriate sections and send in the required supporting documentation, which would be proof of licensure or credentialing. It will tell you on the form what you need to do.

As I mentioned before we'll be overnighting those applications to Noridian Administrative Services and they will be following up and conducting the review. Noridian is our CAP-designated carrier and they process all the claims for the approved CAP vendor and do the enrollment process. They handle the dispute resolution process so they play an important role in the CAP program.

If you receive a request for follow-up information from Noridian please turn it around as quickly as you can. In order to be enrolled as a Medicare supplier all transactions must be completed by the end of April. And please note, if you receive notification from Noridian that you are enrolled as a Medicare supplier for the CAP program that doesn't mean that you've been selected as a CAP vendor. As I mentioned previously this is a two-part process. Noridian enrolls you as a supplier, you would be notified that you had been selected as a CAP vendor and then would have an opportunity to enter into a contract.

If you have any questions about how to fill out the 855 you can direct those to Noridian at their customer contact center. I'll give you that phone number but again there's a link on our Web site. That contact number is (888) 671-0536.

Just a few last things I wanted to mention in terms of working with subcontractors. It is fine if you want to do that but, subcontractors are expected to comply with our regulations as well and provide the same quality of service that the contractor does. We will be looking at the extent of the use of subcontractors. Give us complete information on subcontractors.

Withdrawing a bid – you can decide you want to withdraw your bid prior to contract execution.

And those are the main things I have. So why don't we open it up for questions
Natalie.

Natalie Highsmith: Okay. (Rebecca), if you can just remind everyone on how to get into the queue to ask their question. And please remember when it is your turn you will hear the number that was assigned to you and if you wish you can announce your name and your organization but otherwise you can go ahead and just ask your question anonymously with your number. (Rebecca)?

Operator: At this time I would like to remind everyone if you would like to ask a question press star then the number 1 on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

Your first question comes from line 329. Your line is open.

Man: Yea, hi there. We were actually involved in the bidding the last go around. Is there someplace simple on your Web site that explains the changes to the program since the last CAP bid and the current CAP bid? I've seen a few things here and there on the site but there's not really one good place where I think it's all consolidated.

(Cassie) Black: Well there really aren't that many changes in terms of what you'll be applying for. I mean as (Edmund) said, the documents are basically the same documents. The Excel spreadsheet that you'll fill out has been updated. There's been a change in the way the claims are paid, but that wouldn't effect your applications.

Man: I mean more in terms of economic modeling like that. Does that, how the claims are paid does actually, you know, somewhat, you know, you have to model that properly when you're thinking about this internally.

(Cassie) Black: Well I guess the thing I would do would be to take, as I mentioned, our Federal Register documents that are listed there. You might want to take a look at the Physician Fee Schedule Final Rule which describes the changes that were made by the (TRHCA) legislation. ...

Man: Thank you, I've got that then. Thanks.

(Cassie) Black: Okay.

(Edmund Kasaitis): This is (Edmund Kasaitis). We'll also be releasing a little bit more information on CAP drugs, their usage and physician profiles, kind of a high level thing, but it'll potentially help guide you with some questions that we anticipate you'd have.

Man: Just one last follow-up then – and in terms of the weighting, last time around I think the weights were reflective of total Part B volume. Are these current weights for the next round going to be reflective of CAP experience or of the total Part B (unintelligible).

(Edmund Kasaitis): They are CAP experience.

Man: Oh.

Operator: Your next question comes from line 759. Your line is open.

Line 759, your line is open.

Woman: Hello, can you hear me?

Natalie Highsmith: Yes we can.

Woman: I have two quick questions. My first question is whether the volume of CAP claims from particular types of drugs, will they be a relevant factor in which drugs are included in the next round of CAP solicitations?

(Edmund Kasaitis): I'm not sure if I completely understand your question. If you mean did we eliminate low volume drugs completely the answer is no.

Woman: Okay, that's helpful. And my second question is whether there will be any further changes to clarify whether the CAP model is primarily a distribution system or a specialty pharmacy system.

(Cassie) Black: No the program is what it is. We have implemented the statute. I think the statute was written to allow flexibility and we've operated the program within those parameters since July 1, 2006 and that's the model going forward.

Woman: Okay, thank you very much.

Operator: Your next question comes from line 329. Your line is open.

Man: Yea, and one other follow-up too in terms of how we'd want to economically model this. Are there any statistics going to be available on anything from quarter size experience with co-pay collection from beneficiaries without co-insurance, even the amount of product that goes to say like Samoa or something like that, because that would definitely impact our interest in the plan? And similarly if there's anything that you have around I'd say physician specialties that are not, have not been so interested in CAP to date?

Edmund Kasaitis: We will be providing some information and that will be posted as (Cassie) said towards the end of next week on our CAP Web site. We do not have

analysis complete on very, very detailed data like some of the stuff that you were referring to but we're going to try to provide you with some decent higher level data that should help you paint a picture of what's going on.

Man: Okay, and are you doing anything to target the high drug using specialties like say oncology or urology, ophthalmology, rheumatology, those kind of things? Is there anything specific to those specialties that would make them want to join now that they haven't joined historically?

(Cassie) Black: Well as I said a few minutes ago, we continue to refine the models for the CAP program and trying to make it as physician friendly as we can. We haven't really made specific changes in our CAP drug list to appeal to certain provider types. When we created the list we tried to make it something that would include more commonly used drugs. Is there anything you want to add about the list (Edmund)?

(Edmund Kasaitis): Yes. To springboard off of what (Cassie) said, the vendors are also allowed to request additions to the CAP drug list. So for example if a vendor is contemplating catering to one specific physician community and those drugs are not on the CAP drug list, or certain new drugs have come out on the marketplace, and they might fit in, you can request CMS to add those drugs to your particular drug list.

An addition to your individual drug list doesn't mean the drug will be added to everyone's drug list. We are aware of certain situations where one drug vendor may be less likely or more likely to get certain drugs than other vendors are so we wanted to make that kind of an individual choice for the vendor and give them some flexibility.

Natalie Highsmith: Okay, next question please.

Operator: At this time I would like to remind everyone, if you would like to ask a question press star then the number 1 on your telephone keypad.

Your next question comes from line 431. Your line is open.

Man: Yes. This is kind of a three-part question. But first if someone could just speak to what happened and why the enrollment went from 3,300 in '07 down to 2,300 in '08 here? I know there's going to be another enrollment period, but if someone could speak to that. And then second and third parts of the question are what were the 2008 reimbursement rates based on and what will the 2009 reimbursement rates be based on? Will they be based on this next vendor bidding process?

(Cassie) Black: Well, in terms of your question about the CAP participation figures, this is slightly ahead of where we were last year at this time. I think we're about 300 physicians ahead. What happened was last year we had a special election period after the (TRHCA) changes were implemented. So we fully expect to pick up additional physicians and even more this year. And I'll let (Edmund) respond to your question about the drugs.

(Edmund Kasaitis): Right. The 2008 reimbursement was set by our annual update and that depends on the vendor's cost disclosures for their reasonable net acquisition costs for those drugs. The 2009 reimbursement will be set by the bid prices that we receive and the payment amount limit for Q1 of 2008, calendar year Q1 of 2008.

Man: Thank you.

Operator: Your next question comes from line 329. Your line is open.

Man: Yea. One other question is that I think a lot of the co-pay collection concerns revolve around the types of voluntary physician agreements that can be worked out both in terms of helping collect from the people without co-insurance. Do you have any updated information as to how CMS has viewed those and to make sure that there is no inducements or, I'm just kind of wondering if, have those been common? Is there any information you can give us on that?

(Cassie) Black: We don't have any special information. It's my understanding that most beneficiaries have supplemental insurance policies. So what's happening more frequently I believe is that with most of the claims the beneficiary is not making the co-insurance payment at the time of service but instead that the claim is passing over to the supplemental insurance provider. So we haven't heard that that's been a big issue.

Man: Okay. And the other question just is that compared to the last bidding cycle there seems to be quite a long lag, I mean at least the last time around I think we had fairly recent ASPs. In this case, you know, we'll be going off of a January '08 ASPs for the start of '09. Is there any reason why the bidding is so early in the year compared to the last go around?

(Cassie) Black: We just wanted to allow sufficient time to complete the process and to get the vendors in and trained and to have the information posted on our Web site by September 1 so that physicians could make an informed choice and choose among the vendors.

Edmund Kasaitis: You know the timeframes really are somewhat comparable, we might be one quarter more extended but they're comparable.

Operator: At this time we do not have any further questions in queue.

(Cassie) Black: I just wanted to clarify something I said. The vendor bidding starts on January 14th and it ends on February 15th. I believe I may have misspoken and said January 15th. So that would be a pretty short bidding, one day, so I apologize.

Natalie Highsmith: I guess we can go ahead and end the call. Oh.

(Cassie) Black: Sure. I was going to turn it over to (Bonny Dahm) and she was just going to tell you some of the information that's available on our Web site to guide you as you go through this application process.

(Bonny Dahm): Thanks (Cassie). So to follow up on what was mentioned earlier we have a vendor Web site that is comprised of information left over from the last bidding period, and this will be updated (unintelligible) on the 14th which is next Monday. And so we will post the new bidding documents and also all information pertinent to vendor bidding. You can also get to the other CAP Web sites from the vendor Web site and see the information for physicians page, which lists some training opportunities, new drugs on the CAP drug list and election information. And then (Cassie) also mentioned the (regulation) and notices page where we keep an archive of our published CAP rules. And there will also be an archive on the CAP Web site with all the documents from the 2005 bidding period and so that's available as well.

(Cassie) Black: Great. Well thanks everyone for participating. If you have any questions you can send them in. Our mailbox was listed on the notice, was it not Natalie? Okay.

Natalie Highsmith: So mma303ddrugbid@cms.hhs.gov.

(Cassie) Black: Great. Thanks very much. And then again our CAP Web site is
http://www.cms.hhs.gov/competitiveacqisforbios/03_infovendors.asp.

Bonny Dahm: And just to clarify there's actually (an underscore between 03 and info.

(Cassie) Black: Great.

Bonny Dahm: And this is also when we should probably give out the address for
applications again (unintelligible).

(Cassie) Black: Oh that's a good idea.

Bonny Dahm: And so once more please address applications to CMS, attention Cassandra
Black, Vendor applications, mailstop C40126, 7500 Security Boulevard,
Baltimore, Maryland 21244.

Natalie Highsmith: Okay great. (Rebecca) can you tell us how many joined us on the phones
today?

Operator: 82 ma'am.

Natalie Highsmith: 82, wonderful. Please stay tuned to the list serve and for more information
about the upcoming as to contractor teleconferences and for more information
about the bidding process. Thank you.

Operator: This concludes today's conference call. You may now disconnect.

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